DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 19, 2004

WARNING LETTER
2005– DT-01

Michael J. Burns, PhD
President
Ferndale Laboratories, Inc.
780 West Eight Mile
Ferndale, MI 48220

Dear Dr. Burns:

This letter concerns L.M.X.4 Topical Anesthetic Cream (L.M.X.4), marketed by your firm. Based on the product's label, it is intended for topical over-the-counter (OTC) use as an anesthetic to temporarily relieve pain and itching due to minor cuts, scrapes, burns, skin irritations, and insect bites. These intended uses cause the product to be a drug under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

Promotional materials for L.M.X.4 distributed to physicians' offices and hospitals make statements such as: "For pain associated with. . . Needlesticks . . . Venipuncture. . . Wart removal. . . ."; "Safe for all ages . . . ." ; and "With L.M.X.4, you can make a big difference with your little patients. . . ." The "professional labeling" materials also reference the FDA-approved product EMLA Cream, stating that it requires 60 minutes or longer to work, while L.M.X.4 requires only 30 minutes. Promotional materials on your firm's website www.ferndalelabs.com include identical statements for L.M.X.4. These promotional materials constitute additional evidence of intended uses for your product.

As a condition for marketing L.M.X.4 under FDA' s OTC Drug Review, there must be a precedent product containing 4% lidocaine, marketed in the United States on or before December 4, 1975, with the indications found in L.M.X.4' s labeling. As we are unaware of any such product, L.M.X.4 is not included in the OTC Drug Review. Further, the Tentative Final Monograph (TFM) for External Analgesics (48 Federal Register 5852, February 8, 1983) does not permit indications such as pain associated with needlesticks and venipuncture, nor does it allow "professional labeling" of any kind. L.M.X.4' s use of professional labeling for indications not covered by the TFM is further evidence that the product is not included in the OTC Drug Review.

Because it falls outside the OTC Drug Review, L.M.X.4 is not generally recognized as safe and effective for its labeled indications. Nor are we aware of any data establishing that L.M.X.4 is generally recognized as safe and effective for those indications. Accordingly, it is a new drug as defined by section 201(p) of the Act. Under section 505(a) of the Act, a new drug must be the subject of an

approved application to be legally marketed in the United States. L.M.X.4 lacks an approved application and its marketing in this country violates section 505(a) of the Act.

Moreover, L.M.X.4' s product labeling does not include adequate directions relating to the indications for use that are found on your web site and in the promotional material sent to physicians and hospitals. Accordingly, L.M.X.4 is misbranded under section 502(f)(1) of the Act because the directions for use are inadequate for the intended uses of your product as represented on your website and in your promotional materials.

The violations described above are not meant to be all-inclusive. It is your responsibility to ensure that all drug products manufactured and distributed by your firm comply with the Act. Federal agencies are advised of the issuance of all Warning Letters pertaining to drugs and devices so that they may take this information into account when considering the award of contracts. We request that you take action immediately to correct these violations. Failure to do so may result in regulatory action without further notice, including seizure and/or injunction.

We note that L.M.X.4' s package insert contains the following claims: "L.M.X.4 is unique because it contains tiny microscopic, phospholipids spheres called Accusomes™. Accusomes act as microscopic vessels which help deliver the drug through the skin." In addition, both your Internet site and promotional materials contain the following statements regarding another product, L.M.X..5 Topical Anorectal Anesthetic Cream (L.M.X.5): "L.M.X.5 penetrates quickly due to patented Accusomes . . . Accusomes act as microscopic vessels which help deliver the drug to the site of action. . . . ." These claims suggest either a transdermal or other novel drug delivery system for both products. Such a novel delivery system would cause your products to be new drugs because of the newness of their dosage, or method or duration of administration or application (see 21 CFR § 310.3). We believe that these claims may cause your products to be new drugs. As noted above, under section 505(a) of the Act, a new drug may not be legally marketed in the United States unless it is the subject of an approved application. We request that you address our concern about these drug delivery claims and the new drug status of your products in your response to this letter.

Please send a written response to this office within fifteen working days of receipt of this letter. Your response should describe the specific actions that you will take, or have taken, to correct the violations described in this letter. Your response should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time within which corrections will be completed.

Your response should be directed to Judith Putz, Compliance Officer, Food and Drug Administration Detroit District.

Sincerely,

for David M. Kaszubski
Joann M. Givens
District Director
Detroit District